IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV, and JANSSEN RESEARCH & DEVELOPMENT LLC, *Plaintiffs*, v. MYLAN LABORATORIES LTD., *Defendant*.	Civil Action No. 2:20-cv-13103 (EP)(LDW) FILED UNDER SEAL

PLAINTIFFS' RESPONSIVE POST-TRIAL BRIEF

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TABLE OF ABBREVIATIONS

Citations	
DTX	Defendant's Trial Exhibit (cites to PDF page number)
FPTO	Final Pretrial Order, D.E. 99
JFF	Plaintiffs' Proposed Findings of Fact and Conclusions of Law, D.E. 138
JPB	Plaintiffs' Opening Post-Trial Brief, D.E. 137
MFF & MCOL	Mylan's Proposed Findings of Fact and Conclusions of Law (corrected), D.E. 139
MPB	Mylan's Opening Post-Trial Brief, D.E. 135
PTX	Plaintiffs' Trial Exhibit (cites to PDF page number)
Tr.	Trial Transcript
Parties	
JPN	Janssen Pharmaceutica NV
JPI	Janssen Pharmaceuticals, Inc.
JRD	Janssen Research & Development, LLC
Mylan	Mylan Laboratories Limited
Patent-In-Suit	
693 Patent	U.S. Patent No. 10,143,693
Asserted Claims	Claims 5-7, 9-14
Representative Claims	Claims 5-7, 10 (as representative of claim 9), 11 (as representative of claim 12), 14 (as representative of claim 13)

Defined Abbreviations	
ANDA	Abbreviated New Drug Application
EPS	Extrapyramidal Symptoms
FDA	United States Food & Drug Administration
HCP	Healthcare Professional or Healthcare Practitioner or Healthcare Provider
IM	Intramuscular
LAI	Long-Acting Injectable
LAIA	Long-Acting Injectable Antipsychotic
NDA	New Drug Application
PK	Pharmacokinetics
Pop PK	Population Pharmacokinetics
POSA	Person of Ordinary Skill in the Art
PP	Paliperidone Palmitate
PP1M	Paliperidone Palmitate 1-Month Formulation
PP3M	Paliperidone Palmitate 3-Month Formulation

TABLE OF MYLAN'S PROPOSED LABELS

Mylan's Proposed Labels		
ANDA No. 216228	PTX-92	Paliperidone palmitate 273 mg and 410 mg (or paliperidone 175 and 263 mg eq.)
ANDA No. 212290 (June 2020 version)	PTX-162	Paliperidone palmitate 546 mg (or paliperidone 350 mg eq.)
ANDA No. 212290 (Nov. 2022 version)	PTX-595	Paliperidone palmitate 546 mg (or paliperidone 350 mg eq.)
ANDA No. 215682	PTX-133	Paliperidone palmitate 819 mg (or paliperidone 525 mg eq.)

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JAMA	PTX-113 DTX-26	Berwaerts et al., Efficacy and Safety of the 3-Month Formulation of Paliperidone Palmitate vs Placebo for Relapse Prevention of Schizophrenia, JAMA Psychiatry 72(8) (2015): 830-39
2014 Press Release	PTX-160 DTX-27	Janssen Investigational Treatment for Schizophrenia Shows Positive Efficacy, Delays Relapse (2014)
NCT 423	PTX-158 DTX-21	ClinicalTrials.gov archive, History of Changes for Study: NCT01515423, Study of Paliperidone Palmitate 3 Month and 1 Month Formulations for the Treatment of Patients With Schizophrenia
Invega Sustenna Label	PTX-106 DTX-25	Invega Sustenna Prescribing Information (Rev. 11/2014)
519 Publication	PTX-115 DTX-7	United States Patent Application Publication 2009/0163519 A1
536 Publication	PTX-116 DTX-97	United States Patent Application Publication 2011/0105536 A1
Samtani 2009	PTX-118 DTX-45	Samtani et al., Population Pharmacokinetics of Intramuscular Paliperidone Palmitate in Patients with Schizophrenia: A Novel Once-Monthly, Long-Acting Formulation of an Atypical Antipsychotic, Clin. Pharmacokinet 48(9) (2009): 585-600
Samtani 2011	PTX-161	Samtani et al., Dosing and Switching Strategies for Paliperidone Palmitate: Based on Population Pharmacokinetic Modelling and Clinical Trial Data, CNS Drugs 25(10) (2011): 829-845 and supplemental digital content
Rowland	PTX-145	Rowland and Tozer, Clinical Pharmacokinetics and Pharmacodynamics Concepts and Applications, 4th ed.

Abilify Maintena Label	PTX-168	Abilify Maintena (aripiprazole) Prescribing Information (Rev. 02/2013)
Risperdal Consta Label	PTX-187	Risperdal Consta Prescribing Information (Rev. 6/2014)
Osborne	DTX-36	Osborne et al., Health-related quality of life advantage of long-acting injectable antipsychotic treatment for schizophrenia: a time trade-off study, Health and Quality of Life Outcomes 10(35) (2012): 1-9

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INTRODUCTION

Mylan's Proposed Labels explicitly instruct HCPs to practice the Asserted Claims, and Mylan failed to put forth credible evidence that the Asserted Claims are invalid. As a result, Mylan is liable for inducing infringement of the 693 Patent. Having failed to prove its case at trial, Mylan unleashes a barrage of irrelevant and misleading arguments in its post-trial briefing, while failing to adequately address the relevant facts and law.

Mylan opens its post-trial brief by contending that Janssen is seeking a "nearly 50 year monopoly" on "paliperidone in some form" and that the 693 Patent "thwarts the policy of the Hatch-Waxman Act." MPB at 1. This is wrong. Janssen has no monopoly over technology that is off patent; such technology has been dedicated to the public. Mylan is free to build on Janssen's enormous body of past paliperidone research to develop alternative ways to treat patients with schizophrenia. What Mylan cannot do, at the present time, is copy the precise dosing instructions of the 693 Patent in order to market a generic replica of Invega Trinza®, without conducting any innovative research and development of its own. To do that, Mylan must wait until the 693 Patent has expired. *See* 35 U.S.C. § 271(e)(4)(a). ***That*** is the policy of the Hatch-Waxman Act. The Act does not give Mylan license to infringe a valid patent.

On the relevant questions of infringement and validity, Mylan's arguments

are divorced from the law, unsupported by the trial record, and internally inconsistent. Indeed, there is a fundamental contradiction between Mylan's non-infringement position, which holds that the claimed dosing regimens are so "unreasonable" and "unsafe" that Mylan denies they are even capable of being carried out, and its obviousness case, which contends that the claimed dosing regimens are natural choices that a POSA would have made based on the prior art, before Invega Trinza was available. It is impossible for both of these propositions to be true. In fact, neither is correct.

Mylan's non-infringement arguments are completely unhinged from the language of the Asserted Claims, contrary to the holdings of multiple decisions from courts in this Circuit, and belied by the trial record. Mylan's "divided infringement" theory rests on a logical non sequitur: Because patients perform the action of missing a dose, missing a dose must be a ***step*** of the claimed dosing regimens. This argument does not follow. Under basic claim construction principles, the claimed dosing regimens have three steps, not seven as Mylan contends, so there is no divided infringement on the undisputed facts. Meanwhile, Mylan's argument that its proposed labels do not encourage or recommend to HCPs to practice the Asserted Claims is contrary to the trial record. Mylan's Proposed Labels ***expressly*** do so, and all the expert witnesses, including Mylan's witness Dr. Berger, agreed that some HCPs will follow the labels' instructions.

With respect to obviousness, Mylan simply ignores the many critical defects in its obviousness case that Janssen spotlighted at trial. Mylan spends page after page retreading the obviousness analysis that its expert Dr. Forrest presented on direct examination (an analysis that was admittedly authored by Mylan's counsel rather than by Dr. Forrest himself), but it fails to adequately address the concessions Dr. Forrest made on cross-examination, the multiple instances where he contradicted himself and showed himself to be less than credible, or the contrary testimony of Dr. Sommi. With respect to the 4-to-9 month limitation, for example, Mylan recapitulates Dr. Forrest's hindsight-driven quest to reverse engineer the Asserted Claims, making little effort to address the gaping holes in his testimony. And Mylan fails to provide any reason that a POSA would have used PP1M to reinitiate patients who had previously been advanced to PP3M and missed a dose thereafter. As Dr. Berger testified with great conviction, a POSA would have considered this a "bad idea."

With respect to its defenses under 35 U.S.C. § 112, Mylan similarly fails to come to grips with the trial record. In its post-trial brief, Mylan argues for the first time that the claim terms "PP1M" and "PP3M" have no structural limits, but this was not the opinion Dr. Forrest presented at trial. Dr. Forrest's opinion was that the structural limits of PP1M and PP3M were too broad to enable or adequately describe the claimed formulations. This "in the alternative" opinion, which Dr.

Forrest admitted he did not actually believe, failed to establish non-enablement or lack of written description by clear and convincing evidence. As Dr. Little persuasively testified without genuine contradiction—and with support from documentary evidence including Dr. Forrest's own patents—the structural features in the 693 Patent are entirely adequate to teach a POSA how to make and use the invention. In sum, Mylan failed to meet its burden of proving invalidity.

ARGUMENT

I. MYLAN INDUCES INFRINGEMENT[1]

Mylan's non-infringement arguments rest on a series of sleights of hand and logical non sequiturs, designed to obscure the fact that Mylan's Proposed Labels induce infringement as a matter of law. The Court should reject Mylan's misleading arguments and find that that Mylan's Proposed Labels induce infringement of the Asserted Claims.

A. Mylan's Divided Infringement Theory Fails As a Matter of Law

Mylan's divided infringement theory is a legally defective defense that would have been the subject of dispositive pre-trial claim construction proceedings were it not for the fact that Mylan failed to disclose it in its non-infringement contentions or claim construction exchanges. JPB at 83-84; D.E. 81-1 at 14-19.

[1] All pinpoint citations to exhibits in the record are to PDF page numbers unless otherwise indicated. All emphasis is supplied unless stated otherwise.

The defense fails as a matter of law. JPB at 11-20; JFF 297-305.

1. Mylan Fails to Defend Its Erroneous Seven-Step Construction of the Asserted Claims

In its post-trial brief, Mylan acknowledges that the dispute over divided infringement boils down to "whether the verbiage in the preamble" of the Asserted Claims "is an actual step of the claim, as Mylan contends, or simply a clinical descriptor, as Janssen believes." MPB at 7; *see* JPB at 14, 19. Mylan is correct that, because there is no dispute that HCPs administer the three reinitiation doses of the Asserted Claims (JFF 66, 88-90, 305), the dispositive question on divided infringement is whether the claimed dosing regimens should be construed to have three steps (Janssen's position) or seven steps (Mylan's). JPB at 12. But Mylan fails to engage in a proper claim construction analysis. Applying well-established principles of claim construction, the claimed dosing regimens plainly have three steps, not seven. JPB at 12-19. Mylan's post-trial briefing amounts to an elaborate effort to divert attention from this dispositive claim construction question.

As Judge Cecchi held in an analogous case, determining the number of steps in a claimed method is a question of "claim construction." *In re Biogen '755 Patent Litig.*, No. 10-cv-2734 (CCC)(JBC), 2016 WL 7340311, at *4-5 (D.N.J. Mar. 28, 2016). Although claim construction can sometimes be informed by expert testimony, *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326 (2015), here both parties' experts confirmed that they were ***not*** offering opinions

on claim construction. Tr. 115:23-116:8 (Sommi); 239:8-240:3 (Berger). Accordingly, determining the number of steps in the Asserted Claims involves "much the same task" as "construing other written instruments, such as deeds, contracts, or tariffs." *Teva*, 574 U.S. at 325.

As with other questions of interpretation, claim construction "start[s] with the claim language." *Straight Path IP Grp., Inc. v. Sipnet EU S.R.O.*, 806 F.3d 1356, 1360 (Fed. Cir. 2015); JPB at 13. The specification and prosecution history are certainly relevant, but they are relevant to discerning "what a [POSA] would have understood disputed ***claim language*** to mean." *Schindler Elevator Corp. v. Otis Elevator Co.*, 593 F.3d 1275, 1282 (Fed. Cir. 2010) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc)); *see Aventis Pharm., Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013) ("It is a bedrock principle of patent law that the ***claims*** of a patent define the invention to which the patentee is entitled the right to exclude."). Starting with the claim language, and interpreting the claims in light of the specification and prosecution history, there is simply no way to arrive at the seven-step claim construction on which Mylan's divided infringement theory rests. JPB at 13-19.

In its post-trial brief, Mylan does not even attempt to explain how the disputed claim language—"wherein said patient had been last administered a PP3M injection 4 to 9 months ago"—can reasonably be interpreted to mean that

missing a dose is a step in the claimed dosing regimens, much less how the Asserted Claims can be interpreted to include three additional "return for treatment" steps that are nowhere to be found in the claim language. Instead, Mylan relies on a statement from Janssen's motion *in limine* that steps of a method are "actions" that must be "carried out" for infringement to occur. MPB at 7; MCOL 28. Building on this quote, Mylan proceeds to argue that because missing a dose and returning for treatment are "patient actions" that must occur for the Asserted Claims to be practiced, the acts of missing a dose and returning for treatment must be steps of the claimed dosing regimens. MPB at 8-18.

This is a clever but erroneous sleight of hand. By relying on the quote from Janssen's *in limine* motion, Mylan skips the critical step of assessing what actions are part of the patented method of treatment ***according to the claim language***. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384 (1996) (noting that there are "two elements of a simple patent case, construing the patent and determining whether infringement occurred")*; Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012) ("It is the claims that define the metes and bounds of the patentee's invention."). Janssen's motion *in limine*, of course, provides no support for Mylan's position; Janssen contended there, as it does here, that the "structure and grammar" of the Asserted Claims are the starting point for claim construction. D.E. 81-1 at 6-10. *Limelight Networks, Inc. v.*

Akamai Technologies, Inc., 572 U.S. 915 (2014) does not help Mylan either, as that decision does not address claim construction at all. But these are Mylan's only two citations in support what it terms the "appropriate analysis" for the "determination of a step in a claim." MPB at 7. Mylan's divided infringement arguments lacks any foundation in the law.

Under the proper analysis, determining the number of steps in the claimed dosing regimens involves construing the language of the claims in light of the specification and prosecution history. *In re Biogen*, 2016 WL 7340311, at *4-5. When approached in this manner, there can be no serious question that the steps in the claimed dosing regimens are the three numbered reinitiation doses recited in the Asserted Claims. JPB at 13-19. Courts in this Circuit, when presented with similar disputes, have uniformly come to the exact same conclusion. JPB at 14, 16-17. Notably, these cases have ***expressly*** rejected the argument that because a method-of-treatment claim requires some prior action, that action must be a step of the claimed methods. *See Orexigen Therapeutics, Inc. v. Actavis Lab'ys, FL, Inc.*, 282 F. Supp. 3d 793, 812 (D. Del. 2017) ("A plain reading of this claim limitation indicates that the individual will already be diagnosed prior to the method being performed."), *aff'd in part, rev'd in part sub nom. Nalproprion Pharms., Inc. v. Actavis Lab'ys FL, Inc.*, 934 F.3d 1344 (Fed. Cir. 2019); *In re Biogen*, 2016 WL 7340311, at *5-9 (holding that terms "produced" and "transformed by" were not

method steps because they "describ[e] what 'must ***have been'*** done rather than what 'must ***be***' done").

The principal divided infringement case Mylan relies on, *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017), also supports Janssen's position. MPB at 13-14. In that case, like this one, the claimed methods of treatment comprised three listed administration steps. *Eli Lilly*, 845 F.3d at 1362. Notably, however, nobody suggested that the claimed methods had more than three steps. Rather, the methods were performed by two actors because the first step involved ***self-administration*** by the patient. *Id.* Here, in contrast, all three reinitiation doses are administered by HCPs. JFF 88-90. On the relevant issue of claim construction, *Eli Lilly* stands for what should be an uncontroversial proposition: a method of treatment comprised of administering three doses of medication is a three-step method of treatment. 845 F.3d at 1362. Mylan's seven-step claim construction is baseless.

2. The Fact That Having Missed a Dose Is Required for Infringement Does Not Mean It Is a Step of the Claimed Dosing Regimens

Having sidestepped the claim language, Mylan proceeds to argue that missing a dose and returning for treatment three times are method steps because these activities "must be 'carried out' in order for infringement to occur." MPB at 8-10. Mylan is wrong. It is not unusual for method-of-treatment claims to include

requirements regarding the patients to be treated that are not themselves steps of the method. *See, e.g.*, *Warner-Lambert Co. v. Apotex Corp*., 316 F. 3d 1348 (Fed. Cir. 2003) (claim to "method for treating neurodegenerative diseases" not infringed when defendant used same drug regimen to treat epileptic seizures); JPB at 14. Contrary to Mylan's argument, the fact that the Asserted Claims are not infringed unless the patient received their last dose of PP3M 4 to 9 months ago does not mean that missing a dose is a ***step*** in the claimed dosing regimens. MPB at 8-10.

Mylan concedes that method-of-treatment claims can contain "clinical descriptor[s]" that are not method steps, but argues that this does not apply to the Asserted Claims because "Janssen is disguising . . . patient actions" as "passive." MPB at 12. But it is the claim language, not Janssen, that describes "had been last administered a PP3M injection 4 to 9 months ago" as a characteristic of the patient rather than a step of the claimed dosing regimen. PTX-1 at 21:13-14; JPB at 15. This was the precise holding of *Orexigen*, which rejected a divided infringement defense to a claim for administering a drug "to an individual who has been diagnosed as suffering from overweight or obesity." 282 F. Supp. 3d at 798.

> ***I agree that a diagnosis is required, but I disagree that this comprises a step in the method claim.*** A plain reading of this claim limitation indicates that the individual will already be diagnosed prior to the method being performed. The method itself requires only the single step of administering the drug.

Id. at 812. *See also Bristol-Myers Squibb Co. v. Apotex, Inc*., No. 10-cv-5810

(MLC), 2013 WL 1314733, at *11-15 (D.N.J. Mar. 28, 2013) (rejecting argument that method-of-treatment claims requiring patients to have been diagnosed as treatment resistant before taking claimed medication required "multiple actors").

As for Mylan's argument that the patient must return for treatment in order for the claimed dosing regimens to be administered, this is a background fact true of ***all*** methods of treatment that are administered by HCPs. JFF 74. As Dr. Berger acknowledged, the patient's "cooperat[ion] and consent" is "part of the process for all methods of treatment," and there are many additional steps that "have to happen in the process of any medical procedure." Tr. 299:16-22 (Berger). Mylan does not cite a single case in which a patient's decision to show up for treatment was found to be a step of a claimed method, much less where, as here, that interpretation has no basis in the claim language. *See Bristol-Myers Squibb*, 2013 WL 1314733, at *11-12 (rejecting similar argument). Far from proving the defense, Mylan's "return for treatment" theory is a *reductio ad absurdum* of its divided infringement theory, highlighting how deeply disconnected it is from the language and meaning of the Asserted Claims.

3. Neither the Prosecution History nor the Specification Support Mylan's Seven-Step Claim Construction

As if seeking to persuade through sheer repetition, Mylan contends, again and again, that the prosecution history and the patent specification somehow contradict Janssen's proposed claim construction. MPB at 8-9, 10-11, 14-15, 16-

17. But this contention is simply not true. JPB 18-19; JFF 78-87. Not one of the passages cited by Mylan states that a missed dose is a "step" of the claimed dosing regimens, that the act of missing a dose or returning for treatment are components of the claimed dosing regimens, or that the claimed regimens require seven steps. JFF 78-87. The prosecution history and patent specification are entirely consistent with the claim language, which indicates that a three-step dosing regimen should be administered to patients who miss their doses.

The Prosecution History. Mylan repeatedly cites Janssen's statement in the prosecution history that the "instant claims are solely directed to what patients should do if a dose of PP3M is missed and they desire getting back on the medication," but this passage does not support Mylan's position. MPB at 8-9, 10-11. Janssen obviously was not saying that the claimed dosing regimens are ***administered*** "solely" by patients; it is undisputed that the claimed doses are administered by HCPs. JFF 88-90, 305. Rather, Janssen was distinguishing the PP1M prior art by pointing out that the Asserted Claims are directed solely to the "situation" where the patient has missed a dose of PP3M. DTX-8 at 217; JPB at 19; JFF 84. Indeed, that is precisely what Janssen said, three pages earlier, in the same exhibit that Mylan repeatedly cites. DTX-8 at 214. Mylan has yet to address that statement.

By referring to "what patients should do," Janssen was not asserting that patients carry out the claimed dosing regimens, but rather acknowledging that treatment with PP3M, like any other medical treatment, requires the participation and consent of patients. JFF 87; *supra* at 11. It makes perfect sense, for example, to say that getting a Covid-19 vaccine is something individuals "should do" if they want to reduce the risk of severe illness. This does not mean that a method of vaccinating patients for Covid-19 is carried out by multiple actors. The same is true here. According to the 693 Patent, "what patients should do if a dose of PP3M is missed and they desire getting back on their medication" is go to their HCPs and get treated according to the claimed dosing regimens. DTX-8 at 217. None of this supports Mylan's seven-step claim construction theory.

Meanwhile, Mylan's criticism of Dr. Sommi for not reviewing the prosecution history in connection with his expert report (MPB at 10-11) should have been accompanied by a "chutzpah alert." *Heisman v. Wyndham Vacation Resorts, Inc.*, No. 20-cv-11480 (KM)(JBC), 2021 WL 1138125, at *1 (D.N.J. Mar. 22, 2021). The reason Dr. Sommi did not review the prosecution history is that Mylan failed to disclose a claim construction dispute in its contentions or at the scheduled time to raise claim construction disputes. *See* D.E. 81-1 at 15-17. At trial, Dr. Sommi testified, over Mylan's objection, that the prosecution history Mylan relied on did not change his opinions—as well it should not, for the reasons

given above. Tr. 82:12-83:23 (Sommi). Mylan cannot rely on its own untimeliness to support its meritless divided infringement defense.

The Specification. The specification of the 693 Patent also does not help Mylan. Mylan relies on passages from the specification indicating that the invention covers the situation where a "patient fails to take the next scheduled dose" or "misses [a dose] for a period of between about four months and nine months." MPB at 17. Mylan contends that these passages "could not be clearer" (MPB at 16), but it fails to explain how they support its seven-step claim construction. They do not. The specification simply states that the Asserted Claims are directed to missed doses. JFF 78-81. It does not say that missing a dose, or returning for treatment, are ***steps*** of the claimed dosing regimens. JFF 81.

B. Mylan's Proposed Labels Induce Infringement

Mylan's defense to induced infringement also fails as a matter of law. MPB at 18-29. As Janssen explained in its opening papers, it is aware of no case in which a label's ***explicit*** instructions to infringe were found non-infringing. JPB at 23; *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp. 3d 352, 399 (D.N.J. 2018) ("Proposed labeling that instructs [an] infringing use[] is generally sufficient to support a finding of intentional inducement."), *appeal dismissed in relevant part as moot*, 923 F.3d 1063 (Fed. Cir. 2019). As with divided infringement,

Mylan's arguments concerning non-inducement seek to distract attention from its meritless position. None of Mylan's arguments holds water.

1. Mylan's Proposed Labels Instruct Infringement

Mylan contends that its copying of the Invega Trinza label is not by itself sufficient to establish induced infringement, but this misses the point. MPB at 18-19. The question is not whether the accused labels copy Janssen's ***product***, but rather whether they encourage infringement of Janssen's ***patent***. The undisputed facts show that they do both these things. JPB at 10-11; JFF 43-62, 91-98.

[redacted] JFF 49; Tr. 1038:2-14 (Berger). This, of course, is highly relevant to infringement. JPB at 11. Mylan's argument that copying the Trinza label does not induce infringement is a red herring.

Contrary to Mylan's contention, moreover, its proposed labels do not discourage infringement[redacted]. MPB at 28-29. [redacted]. When doses are missed, and the undisputed evidence shows that they often are (JFF 95-96), Mylan's Proposed Labels expressly ***encourage*** infringement. This distinguishes *Takeda Pharms. USA, Inc. v. West-Ward Pharm. Corp.*, 72 F. Supp. 3d 539, 547 (D. Del. 2014), where the label instructed that the claimed method ***itself*** should be avoided. [redacted]

[redacted].

2. Infringing Instructions Do Not Need to Be in the "Indications and Usage" Section of a Drug Label

Mylan's argument that it does not induce infringement because its infringing instructions are not found in the "Indications and Usage" section of its proposed labels is equally baseless. MPB at 19-20. There is no "indications and usage" requirement for induced infringement under 35 U.S.C. § 271(b). JPB at 9-10; JFF 292-294. In cases concerning drug labels, it is the ***label*** that is relevant to infringement. *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd*., 887 F.3d 1117, 1129 (Fed. Cir. 2018) ("When proof of specific intent depends on the label accompanying the marketing of a drug inducing infringement by physicians, 'the ***label*** must encourage, recommend, or promote infringement.'") (cleaned up).

The cases Mylan relies on do not support its argument. MPB at 20. In those cases, the question of infringement turned on identifying the recommended indication in the label, so naturally the "Indications and Usage" section was important.[2] But none of them holds that "Indications and Usage" section is central to ***all*** method of treatment claims. To the contrary, one of Mylan's cases expressly

[2] *See Sanofi v. Watson Lab'ys Inc*., 875 F.3d 636 (Fed. Cir. 2017); *BTG Int'l*, 352 F. Supp. 3d at 392; *Bayer Schering Pharma AG v. Lupin Ltd*., 676 F.3d 1316, 1321 (Fed. Cir. 2012).

notes that "an FDA-approved method of use relating to the dosage or method of administration of a drug would appear ***not in the Indications and Usage section***, but in the 'Dosage and Administration' section of the label." *Bayer Schering*, 676 F.3d at 1323.

[redacted] JFF 45-46; *e.g.*, PTX-92 at 1, 6-7. This is precisely analogous to the *Sanofi* case relied on by Mylan, where infringement was found when the "Indications and Usage" section referred to a "Clinical Studies" section, which in turn contained the infringing information. *Sanofi*, 875 F.3d at 645-46. In short, the very cases Mylan relies on for its non-inducement argument demonstrate why induced infringement is present here.

3. Substantial Non-Infringing Uses Do Not Defeat Induced Infringement

As Janssen showed in its opening brief, the law is clear that, "even if the proposed ANDA product has 'substantial noninfringing uses,'" the ANDA applicant "may still be held liable for induced infringement." *Vanda*, 887 F.3d at 1133; JPB at 26-27. In its post-trial brief, Mylan contends that there are substantial non-infringing uses of PP3M, but it cites no case law holding that this forecloses induced infringement. MPB at 20-21. The only case Mylan relies on, *HZNP Meds. LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 702 (Fed. Cir. 2019), is

inapposite. JPB at 22. In that case, the accused label did not instruct users to infringe; it only "require[d] the first step of [the claimed] method, nothing else." *HZNP*, 940 F.3d at 702. Here, Mylan's Proposed Labels expressly instruct HCPs to practice every element of the Asserted Claims for patients who last received a dose of PP3M 4-9 months ago. JFF 91-93. Mylan therefore induces infringement, notwithstanding the fact that the labels also contain instructions pertaining to different clinical situations.

4. The Record Is Clear That Some HCPs Will Follow the Instructions in the Label

As Janssen showed in its opening papers, the trial record is clear that the 4-to-9 month clinical situation addressed by the Asserted Claims is not uncommon, and that many HCPs will practice, and indeed have practiced, the Asserted Claims in that situation. JPB at 23-25; JFF 94-98. Mylan's contention that infringement is not inevitable is contrary to the trial record—including the testimony of its own expert, Dr. Berger. MPB at 22-28.

As a preliminary matter, Mylan's argument that infringement cannot be established without providing examples of past infringement is contrary to the law. MPB at 23-26. The law is clear "that a patentee does not need to prove an actual past instance of direct infringement by a physician to establish infringement under 35 U.S.C. § 271(e)(2)(A)." *Vanda*, 887 F.3d at 1129. And the record is clear that it is not uncommon for patients to return for treatment 4-9 months after their last

dose of Invega Trinza. JPB at 23-25; JFF 96. The testimony of Dr. Sommi—and Mylan's own corporate witness—that HCPs will follow the explicit instructions of Mylan's Proposed Labels in this situation, and thereby infringe the Asserted Claims, establishes that Mylan induces infringement. JPB at 25-26.

Furthermore, Mylan ***concedes*** that the trial record contains evidence that the Asserted Claims have been practiced in the past. MPB at 25 n.11. As Mylan acknowledges, Dr. Kohler testified as much. JFF 97. Mylan's suggestion that the Court should ignore this evidence because it was introduced in connection with objective indicia of nonobviousness requires another "chutzpah alert." *Heisman*, 2021 WL 1138125, at *1. Mylan ***affirmatively argues*** that "Janssen chose to forego any testimony from a prescribing physician who had or would follow the claimed missed-dose regimen." MPB at 25. Having placed the matter at issue by making this false assertion, Mylan cannot prevent Janssen from pointing out that the assertion is flatly untrue. *See, e.g., P&G v. Nabisco Brands, Inc.*, 604 F. Supp. 1485, 1492 (D. Del. 1985) ("P&G's evidence on the commercial success of its product is relevant both to the issue of obviousness under section 103 and to the issue of infringement.").

Not even Mylan's expert, Dr. Berger, denied that some HCPs would practice the Asserted Claims. To be sure, Dr. Berger testified vehemently that the claimed dosing regimens are "a bad idea," "unsafe," and "unreasonable," and that he has

never used them.[3] JPB at 55. Mylan endorses Dr. Berger's view of the Asserted Claims in its brief (MPB at 24-25), thereby undermining its own obviousness case. *See infra* at 31-33, 47-48. On cross-examination, however, Dr. Berger conceded that some HCPs would try to practice the Asserted Claims (Tr. 263:16-19), and while he pointed out that they would fail "if the patient doesn't show up," he acknowledged that "[s]ometimes patients show up." Tr. 263:22-264:2 (Berger). The record is therefore undisputed that some HCPs will practice the Asserted Claims according to Mylan's explicit instructions.[4] This establishes induced infringement. JFF 94-98, 312.

II. MYLAN FAILED TO ESTABLISH OBVIOUSNESS

Mylan spends most of its post-trial brief reiterating the opening obviousness case it presented at trial, without addressing the contrary evidence Janssen presented or the holes and inconsistencies that were revealed in Dr. Forrest's theories. MPB at 29-64; *see* JPB at 27-58. The numerous contradictions in Dr. Forrest's opinions and his unscientific and hindsight-driven analyses are simply

[3] Mylan misleadingly asserts that Dr. Berger has never used the Asserted Claims despite having treated "tens of thousands of patients." MPB at 24-25. Dr. Berger testified, however, that he has only treated "about 50 to 100 patients" with Invega Trinza. Tr. 1050:23-25 (Berger).

[4] Although Dr. Berger denied on direct examination that infringement was inevitable, the reasoning he gave for this was that "to say that something is inevitable is to predict the future." Tr. 231:18-232:4 (Berger). Dr. Berger did not actually deny that HCPs would practice the Asserted Claims.

ignored. Mylan's failure to address contrary facts and testimony precludes a finding of obviousness by clear and convincing evidence.

A. Mylan's Failure to Identify All Elements of the Asserted Claims in the Prior Art Defeats Its Obviousness Case

Mylan "concedes," as it must, that key elements of the Asserted Claims are missing from the prior art. MPB at 66; JPB 30-31. In particular, no prior art disclosed (a) a missed dose regimen for PP3M, (b) administered to a specific patient population whose last dose of PP3M was 4 to 9 months ago, (c) treating the patient, who had been advanced from PP1M to PP3M, with PP1M reinitiation loading doses, or (d) returning the patient to PP3M treatment without first stabilizing the patient on PP1M for several months. JPB at 30-31; JFF 326. Dr. Forrest admitted each of these gaps in the prior art at trial. JPB at 30-31; JFF 326.

Mylan attempts to minimize these critical admissions by contending that whether or not the "prior art disclosed *exactly* what is claimed" is only relevant to anticipation and not obviousness. MPB at 66 (emphasis in original); *id*. at 30. Mylan is mistaken. To establish anticipation, "the proponent must show that the four corners of a ***single, prior art document*** describe every element of the claimed invention," "arranged as in the claim." *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (internal quotation marks omitted). But where, as here, elements of the claimed invention are not present in ***any*** prior art reference, that is undeniably relevant to obviousness. JPB at 30-31; JFF 326.

"When an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references." *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1368 (Fed. Cir. 2016) (internal quotation marks omitted). But, unless each claim limitation is disclosed ***somewhere*** in the prior art, a POSA cannot combine prior-art references to arrive at the claimed invention. Thus, to establish that there would have been a motivation to combine references to arrive at the claimed invention, Mylan had the "burden to prove that ***all*** claimed limitations are disclosed in the prior art." *Par Pharm. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1194 (Fed. Cir. 2014). *Par*, as well as *University of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 160 (Fed. Cir. 2021), that Janssen relied on for this point, involve obviousness, not anticipation. JPB at 28-29. Mylan's contention that this principle is only applicable to anticipation is simply not correct.

In re Merck & Co., 800 F.2d 1091, 1097 (Fed. Cir. 1986), on which Mylan relies, is inapposite. MPB at 65. *Merck* holds that the shortcomings of an ***individual*** prior art reference cannot defeat an obviousness rejection "where the rejection is based upon the teachings of a combination of references" and the "prior art as a whole" taught the claimed invention. 800 F.2d at 1097. Here, in contrast, Dr. Forrest admitted that key elements of the Asserted Claims are missing from the prior art ***as a whole***—not just from certain individual references. JPB at 30-31;

JFF 326. Moreover, as Janssen showed in its opening brief and Mylan fails to refute, the "common knowledge" exception to the burden of showing that all elements are present in the prior art does not apply here. JPB at 31-32. Mylan's obviousness case therefore fails.

B. Mylan Fails to Defend the Credibility of Dr. Forrest's Hindsight-Driven Quest to Recreate the 4-to-9 Month Window of the Asserted Claims

Mylan also failed to show that a POSA would have been motivated to combine prior art references to arrive at the Asserted Claims with a reasonable expectation of success. JPB at 32-58. To meet this burden, Mylan relied on the opinions of Dr. Forrest, who testified at length about how he believed a POSA could have arrived at certain aspects of the claimed invention. But as Janssen showed in its opening brief, Dr. Forrest's analysis was a transparent effort to recreate the Asserted Claims from the prior art using hindsight; it did not represent a credible account of what a POSA would have known ***prior to*** the time of the invention, without using the 693 Patent as a guide. JPB at 34-38.

In its post-trial briefing, Mylan retraces Dr. Forrest's journey to reverse engineer the 4-to-9 month patient population, MPB at 56-62, without addressing the multiple contradictions in his analysis, let alone explaining away the fundamentally hindsight-driven nature of the exercise. JPB at 38-51. Dr. Forrest's unscientific assumptions and repeated reliance on hindsight at trial to get to the 4-

to-9 month patient population preclude finding clear and convincing evidence on motivation and a reasonable expectation of success. *Id.*

1. Invega Sustenna Label Extrapolation Theory

As Janssen established in its opening, a POSA would not have relied on the Invega Sustenna Label to guess what a missed dose regimen for PP3M should be. JPB at 39-40. But even assuming counterfactually that they would, a POSA would certainly have used the same approach to calculate the front end and the back end of the dosing window, rather than selectively using the reference for the front end but not the back end as Dr. Forrest did. JPB at 40. In its post-trial brief, Mylan fails to address this criticism. *See* MPB at 56-62. Mylan argues that a POSA would have relied on the label for the 4-month front end, but would have rejected the 18-month back end because 18 months is a "significant amount of time without a dose," and a POSA would choose a shorter time in an effort to prevent relapses. MPB at 58. But Mylan fails to explain why, if a POSA believed that extrapolating from the PP1M label did not work to predict the back end of a missed dose window for PP3M, they would have used this method to predict the front end. JPB at 40. In short, Mylan doubles down on selective hindsight, ignoring the principle that the "prior art must be considered for all its teachings, not selectively." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019).

2. 4-5 Half-Life Extrapolation Theory

At trial, Dr. Forrest pivoted to his 4-5 half-life theory in an unsuccessful attempt to move closer to the 9-month endpoint. JPB at 41-42. Tellingly, Mylan does not even mention this theory in its brief, perhaps realizing that the unscientific assumptions and missteps made in advocating the 4-5 half-life theory hurt the credibility of its case more than help Mylan's quest to reach the 9-month back end of the Asserted Claims. *Id.*

Mylan does briefly mention the theory in its proposed findings of fact, but without addressing its many faults. *See* MFF 140-148, 392-395. For example, Mylan continues to erroneously insist that the half-life of PP1M is 33 days, pointing to an unspecified "underlying source," MFF 142; but 33 days is nowhere taught or suggested in the prior art. JFF 131; s*ee* PTX-115 ¶ [0098] (reporting PP1M half-life as "from 25 days (median) after the 25 mg eq. dose to 40-49 days (median) after the 100 and 150 mg eq. dose, for both injection sites."); PTX-106 at 40 ("ranged from 25 days - 49 days").[5]

The upshot of Mylan's half-life exercise is to contend that the half-lives of PP1M and PP3M can be assumed based on their dosing intervals—30 days and 90

[5] In another pass at this, Mylan argues that Samtani 2009 and Samtani 2011 each taught that the PP1M half-life is about 30 days. MFF 143, 147. *See* Tr. 781:17-22 (Forrest). But Samtani 2009 lacks any reference to PP1M half-life (*see* PTX-118), and Samtani 2011 relayed a PP1M half-life similar to the 519 Publication. *See* PTX-161 at 13 ("varies from 25 to 49 days over the dose range of 25-150 mg eq.").

days, respectively—and that a POSA could build on this speculative and unreliable foundation to estimate the 4-to-9 month dosing window of the Asserted Claims. MFF 148, 392-395. But this theory not only fails to point a POSA to the Asserted Claims (JPB at 41-42), it contradicts Mylan's other theories, including Dr. Forrest's own modeling results, which assume a half-live of 60 days and 179 days, for PP1M and PP3M, respectively. JPB at 49-50; *see infra* 28-29. Mylan's internally contradictory obviousness case is not credible.

3. Extrapolation from JAMA

Mylan also fails to defend Dr. Forrest's third incredible attempt to reconstruct the 4-to-9 month window: his reliance on the JAMA paper. *See* JPB at 42-46. As Dr. Sommi explained at trial, a relapse study like JAMA provides little (if any) information on designing missed dose regimens (JPB at 43), and Dr. Forrest's opinions on the issue were riddled with scientifically groundless maneuvers to arrive at his intended target. *See* JPB at 36-37, 42-46.

The first groundless move in Dr. Forrest's JAMA analysis was his decision to use the interim rather than final data from JAMA, notwithstanding his admission that a POSA would "use all the data you had at hand." JPB at 44; JFF 141-142. Mylan argues that since JAMA labeled the interim analysis as the "primary" analysis, a POSA would use that instead of the final analysis. MBP at 47, 58. But this argument was persuasively refuted by Dr. Sommi, the only trial witness with

experience running schizophrenia clinical trials. JPB at 43; JFF 146. The interim analysis is called the primary analysis because, as Dr. Sommi credibly explained, it is the analysis performed at a predetermined timepoint when patients will cease to be given placebos if the PP3M treatment shows efficacy. JFF 143. But even after efficacy is established, data continues to be collected, resulting in a final analysis. JFF 143. From the perspective of a scientist reviewing the data from the study after it is completed, there is no legitimate reason to ignore this final data—other than the fact that the interim data gets Dr. Forrest to a point closer to the Asserted Claims. JFF 143; JPB at 44.[6]

Then came Dr. Forrest's infamous "natural jump" theory, which he improvised on the fly to correct his pretrial misreading of JAMA. JPB at 36-37, 44-45. In an effort to retrofit a scientific basis to the "natural jump" theory, Mylan argues that a POSA could have used data in the Invega Sustenna (PP1M) label, showing a median time to relapse of 193 days, to identify a "jump" in PP1M, which could then be extrapolated to PP3M. MPB at 59; MFF 411. This retroactive justification does not fly. The back end of the intermediate window of the Invega Sustenna label's missed dose regimen is 6 months, or 183 days. JPB at 39-40. If the Invega Sustenna label's 193-day median time to relapse were used to

[6] *See also* PTX-113 at 3 ("Results through the end of the DB phase after early termination of the study (i[.]e[.], cumulative data including those from before the interim cutoff data) are reported herein as the final analysis . . . .").

identify a purported "jump," it would be a "jump" of 10 days (193 - 183). Dr. Forrest's "natural jump" for PP3M, in contrast, was 94 days (274 - 180), almost an order of magnitude larger. JPB at 45. Dr. Forrest's "natural jump" was a hindsight-driven effort to arrive at the Asserted Claims, not a legitimate account of what a POSA would have done. Once again, Dr. Forrest's obviousness analysis is not credible.

4. Mylan Failed to Address the Contradictions and Flaws Called Out Against Dr. Forrest's PK Modeling

Another fatal defect in Mylan's obviousness case is its continued reliance on Dr. Forrest's unscientific, flawed, and hindsight-driven PK modeling. MPB at 59-61. Janssen established at trial that Dr. Forrest's modeling is fraught with unscientific assumptions, indefensible inconsistencies, and results-oriented analyses. JPB at 46-51. Mylan simply brushes this away, reiterating that Dr. Forrest's discredited modeling "validated" the 9-month endpoint. MPB at 59-61.

Mylan fails to defend Dr. Forrest's modeling from Janssen's cogent criticisms. Mylan does not even attempt to justify Dr. Forrest's failure to use his modeling to estimate the 4-month starting point of the missed-dose window, acknowledging that it is "especially" directed to the "nine-month endpoint." MPB at 59. Mylan insists that Dr. Forrest's flawed PK model "is spot-on" during the elimination phase. MPB at 60-61. But as Janssen has demonstrated, Mylan's model is not "spot-on," even by its own cherry-picked criteria. JFF 166-180. Dr.

Forrest's model predicted that a PP3M injection in the gluteal has a half-life of about 179 days, which is two times longer than the 90-day half-life he assumed for identifying the 4-to-9 month patient population, and which is substantially different from the 120 to 140 days reported in the non-prior art PP3M data. JPB 49-50. Neither of these critical inconsistencies is addressed in Mylan's post-trial brief or findings of fact.

Similarly, Mylan's contention that Dr. Forrest "validated" his PP1M model by comparing it to the actual plasma levels of PP1M, (MPB at 60), is belied by the fact that Dr. Forrest's predicted half-life for PP1M (60 days) falls well outside the known, actual half-life range (25-49 days). JPB at 49-50. As Dr. Gobburu explained, "there is a discordance" between Dr. Forrest's model and the actual PP1M data that is far greater than what a POSA would accept as validation. JFF 176. It is not surprising that Dr. Forrest's models failed all validation efforts, because they are based on unscientific extrapolations and erroneous assumptions. JPB at 46-50; JFF 152-180. Once again, none of these inconsistencies were addressed by Mylan.

Mylan's only response to Dr. Gobburu's criticisms is that Dr. Gobburu relied on his experience as a scientist working in the field, rather than imagining himself as a "hypothetical" POSA, and that he was not asked to review all the prior art cited by Dr. Forrest. MPB at 61-62. But, unlike Dr. Sommi, who reviewed all

of Dr. Forrest's prior-art references, Dr. Gobburu, a modeling expert, was only asked to comment on Dr. Forrest's modeling. *Cf. Birchwood Lab'ys, Inc. v. Battenfeld Techs., Inc.*, No. 09-cv-3555, 2012 WL 2045757, at *8 (D. Minn. May 21, 2012) (finding testimony of an "expert in a pertinent aspect of the relevant art, although not an expert in the entire field art" is "relevant and useful"). In doing so, Dr. Gobburu considered Samtani 2009, which, as Dr. Forrest admitted on cross-examination, was the sole reference he pulled data and information from to build his models. Tr. 724:9-14 (Forrest).[7] Dr. Gobburu therefore considered all "***the relevant prior art***" to his opinions. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *cf.*, *Hologic, Inc. v. Minerva Surgical, Inc.*, 764 F. App'x 873, 881 n.8 (Fed. Cir. 2019) (experts need not "review[] the prior art references at issue" to opine on certain topics in the obviousness case).

Mylan's response to Dr. Gobburu's opinions is conspicuous for what it does ***not*** include: any substantive defense of Dr. Forrest's unscientific modeling exercise. This only confirms how thoroughly Dr. Gobburu discredited Dr. Forrest's hindsight-driven modeling analysis. JPB at 46-50; JFF 152-180. Dr. Forrest's flawed theories cannot support Mylan's burden of establishing

[7] Citing JAMA at 4, Mylan asserts that JAMA "disclosed mean plasma profiles" but that is a misstatement. MFF 432; *see also* PTX-113 at 4; Forrest Demonstratives Slide 65. When Dr. Forrest testified about "mean plasma profiles" he was referring to Figure 1 of Samtani 2009 and nothing else. Tr. 506:11-22 (Forrest); Forrest Demonstratives Slide 65.

obviousness.

C. Mylan Failed to Establish a Motivation to Use PP1M to Reinitiate Patients Who Had Been Successfully Advanced to PP3M

In addition to the 4-to-9 month time window, Mylan failed to prove that a POSA would have been motivated to use PP1M to treat a patient who had been successfully advanced to PP3M. JPB at 54-58; *see supra* 21. Mylan seeks to fill this gap in the prior art by relying on the fact that PP1M is used to initiate patients who had ***not*** been advanced to PP3M, and arguing that PP1M would be seen as "faster-acting" than PP3M. MPB at 55-56, 66-67. Mylan's argument fails on two counts: (1) it is contrary to the opinion of Mylan's physician expert Dr. Berger, who testified that using PP1M to reinitiate PP3M patients would have been considered a "bad idea"; and (2) it is contrary to the modeling and simulations presented by Dr. Forrest indicating that ***PP3M*** would have been faster acting. JPB at 54-58; JFF 191-204.

1. Mylan's Own Clinical Expert Testified That a POSA Would Not Have Used PP1M to Reinitiate a Patient on PP3M

Mylan argues that because PP1M is used to ***initiate*** patients who have not previously been treated with PP3M, and to ***reinitiate*** PP1M patients back to ***PP1M***, it would have been obvious to use PP1M to ***reinitiate*** patients back to ***PP3M***. MPB at 55-56, 66-67. According to Mylan, the use of PP1M in these contexts would have applied equally to PP3M reinitiation because "[t]here is no

difference in the drug concentration in the body for patients in the middle window regardless of whether they were being treated with PP1M or PP3M." MPB at 55. That statement is entirely unfounded. With no prior-art information about PP3M pharmacokinetics (JFF 197) or PP3M missed dose instructions (JFF 326), there would have been no way to predict a middle window or drug concentration in the body for PP3M, notwithstanding Dr. Forrest's hindsight-driven attempts to do so. Furthermore, there was nothing in the prior art that suggested using two different LAI formulations to manage a missed dose, let alone backtracking to PP1M once advanced to PP3M. JPB at 54-55. As Dr. Sommi testified, if anything, the Invega Sustenna Label, on which Mylan relies, suggested treating the patients who missed PP3M with "the dose of PP3M that they missed." JPB at 54-55.

Critically, Dr. Berger, the only expert presented by Mylan who had any prior knowledge of schizophrenia or experience treating patients, wholeheartedly ***agreed*** with Dr. Sommi on this point. As discussed in Janssen's opening papers, Dr. Berger testified that, at the time of the 693 Patent, treating a patient who had missed a dose of PP3M with multiple reinitiation doses of PP1M would have been considered "a bad idea" that was "unsafe" and "unreasonable," and that it would have been "far wiser" simply to reinitiate nonadherent patients using PP3M. JPB at 55. In its post-trial brief, Mylan embraces Dr. Berger's point of view in connection with its non-infringement case, asking rhetorically "what non-adherent

patient is going to magically become adherent for three subsequent injections: two injections one week apart and a third a month later?" MPB at 2. Mylan ignores that this is powerful affirmative evidence that a POSA would ***not*** have been motivated to, nor would have reasonably expected success in, using PP1M to reinitiate patients who missed doses of PP3M. JPB at 55-56. The fact that it comes from Mylan's own expert is damning to Mylan's obviousness case. *See, e.g.*, *Nichia Corp. v. Everlight Ams., Inc.*, 855 F.3d 1328, 1337 (Fed. Cir. 2017) ("admission" by patent challenger's expert indicated that there is "no motivation to combine"); *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1358-60 (Fed. Cir. 2007) (admissions that the purported lead compound had "negative side effects" and would have been seen as "undesirable" supported challenger's failure to prove obviousness).

2. Nothing in the Prior Art Taught That PP1M Was Faster Acting Than PP3M

Mylan also contends that a POSA would have been motivated to reinitiate with PP1M because it was seen as faster acting than PP3M. MPB at 67. But as Janssen showed in its opening papers, since the prior art lacked PK data about PP3M, a POSA would have had no reason to believe that PP1M would reach therapeutic concentrations faster than PP3M. JPB at 56-57. Indeed, [redacted], Mylan's witness admitted that "without measuring the blood level, [they] wouldn't know in any

way . . . what Mylan's proposed PP3M PK profile would look like." JFF 168 n.15. None of this evidence is addressed by Mylan.

Although a POSA would have known that a three-month product by definition lasts longer than a one-month product, this does not necessarily mean that it would reach therapeutic levels more slowly. JFF 196; Tr. 595:4-7 (Sommi). Since the PK of PP3M was unknown, a POSA would have had no way of knowing how PP3M would behave in the initial phase. JPB at 55-56. A POSA therefore would have had no way to know whether PP3M was faster or slower than PP1M in the initial phase and would have had no motivation to use PP1M rather than PP3M to treat patients who missed doses of PP3M.

Moreover, as both parties' experts acknowledged, PP1M's fast initial efficacy comes from an "initial burst" of concentration that follows complex and unpredictable PK principles. JPB at 48-49; JFF 162-165, 196. Dr. Forrest acknowledged that a POSA would have known that that could be the case for PP3M. JPB at 49; JFF 163. The complex and unpredictable absorption characteristics of paliperidone palmitate at the initial phase means that the initial rate of absorption cannot be predicted based on overall particle size difference. JPB at 56.

Additionally, the PK modeling exercise that Dr. Forrest presented to "validate" his opinions confirmed that a POSA could ***not*** have predicted that

PP1M would be faster acting than PP3M. JPB at 52-53. On its face, Dr. Forrest's modeling and related graph indicate that PP1M and PP3M are equally fast-acting, even when presenting a biased, apples-to-oranges comparison of deltoid injections of PP1M with gluteal injections of PP3M. JPB at 52-53; JFF 199-200. As Dr. Forrest admitted on cross, if he had made an apples-to-apples comparison of the two formulations in the same injection site, ***PP3M*** would have been faster in reaching therapeutic concentrations than PP1M. JPB at 53. This directly undermines Mylan's argument that a POSA would have been motivated to use PP1M because it was faster acting. JPB at 57. This is yet another point Janssen openly developed at trial (JFF 199-202) that is ignored in Mylan's briefing.

D. Mylan Failed to Establish a Motivation to Administer PP3M Without Stabilizing Patients on PP1M for Several Months

Mylan barely addresses the last missing key element from the prior art, namely, returning the patient to PP3M treatment without first stabilizing the patient on PP1M for several months. MPB at 67-68. The trial record clearly shows that each PP3M reference (JAMA, NCT 423, and the 2014 Press Release) required patients to be stabilized on PP1M for at least 4 months before advancing to PP3M. JFF 205. Mylan presented no evidence that a POSA would have been motivated to ignore this teaching.

In its post-trial brief, Mylan contends that requiring patients to remain on PP1M for at least 4 months "would not make sense" for PP3M missed doses,

because the prior art applies to patients who were naïve to paliperidone, whereas a PP3M reinitiation regimen applies to patients who may have paliperidone in their system. MPB at 67. But that misses the point entirely. The question is—when is it appropriate to advance a patient to PP3M? The prior art requires the patient to be stabilized on PP1M for at least four months before being eligible for advancement to PP3M. Mylan has not presented any justification for departing from this prior art teaching. JFF 205. This, again, violates the principle that prior art must be considered for "all its teachings, not selectively." *Henny Penny*, 938 F.3d at 1332. To the extent that a POSA would have relied on JAMA and NCT 423 to select PP1M for a PP3M reinitiation regimen (which as discussed above they would not), they would have found no reason to ignore the requirement that patients be stabilized on PP1M for at least four months before being advanced to PP3M. JFF 206.

E. Mylan's Legal Arguments Fail to Support Its Case

For the reasons discussed above and in Janssen's opening papers, Mylan failed to meet its burden of proving obviousness at trial. None of the legal arguments on which Mylan relies in its post-trial briefing succeeds in salvaging its failed obviousness case.

1. Mylan Cannot Rely on a Presumption of Obviousness to Reach the 4-to-9 Month Missed Dose Window

Recognizing the weakness of Dr. Forrest's hindsight-driven exercise to get

to the endpoints of the 4-to-9 month window of the Asserted Claims, Mylan attempts to shift the burden of proof to Janssen. MPB at 63-64. Mylan argues that, even if the 4-to-9 month window would not have been obvious, it was supposedly undisputed that a "middle window" starting at "five or six months" would have been obvious. MPB at 63. From there, Mylan contends, a POSA could have relied on "routine optimization" to arrive at the Asserted Claims, supposedly triggering a "presumption of obviousness" that exists when a claimed invention falls within a numerical range disclosed in the prior art. MPB at 64. This argument is contrary to the facts and the law.

On the facts, Dr. Sommi did ***not*** testify that a five to six month starting point, or any other part of a PP3M missed dose window, would have been obvious. MPB at 63. To the contrary, Dr. Sommi testified forcefully that each one of Dr. Forrest's hindsight-driven efforts to arrive at the 4-to-9 month window was unreliable and would never have been used by a POSA. JFF 127, 129, 147, 177-180. Dr. Sommi went on to explain that, even using Dr. Forrest's flawed methodology, a POSA could not have arrived at 4- and 9-month endpoints as Dr. Forrest suggested. JPB at 40, 42, 44-46; JFF 125, 137, 151, 189-90. In offering these latter opinions, Dr. Sommi did not concede that ***any*** missed dose window for PP3M would have been obvious. Mylan's reliance on a supposed "agreement" between the experts is completely unsupported by the trial record. MPB at 63.

On the law, Mylan is equally wrong. Mylan cites *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955) and *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006 (Fed. Cir. 2018) to argue that there is a presumption of obviousness when the numerical ranges in a claim "overlap the ranges disclosed in the prior art." MPB at 64. But, as the Federal Circuit recently explained, this presumption is limited to the situation "when the ranges of a claimed composition overlap the ranges ***disclosed*** in the prior art." *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1364, 1373 (Fed. Cir. 2021) (emphasis in original) (quoting *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003)). The Federal Circuit has "never before applied the presumption of obviousness for overlapping ranges in a case in which the prior art does ***not*** contain an express disclosure of a range." *Id*. Here, as Dr. Forrest admitted, there was no prior-art disclosure of ***any*** missed dose window for PP3M. JPB at 30-31; JFF 326. Rather, Dr. Forrest attempted to derive the missed dose window from disparate references that had nothing to do with missed doses of PP3M. Because the 4-to-9 month missed dose window does not overlap with any range ***disclosed*** in the prior art, there can be no presumption of obviousness.

Furthermore, no presumption of obviousness applies "[w]here an invention is contended to be obvious based upon a ***combination*** of elements." *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1320 (Fed. Cir. 2004). Rather,

"the presumption attaches only when the range or value of a particular variable is ***the*** difference between the claimed invention and the prior art." *Tris Pharma, Inc. v. Actavis Lab'ys FL, Inc.*, 503 F. Supp. 3d 183, 203 (D. Del. 2020) (emphasis in original) (internal quotation marks omitted), *aff'd*, No. 2021-1495, 2022 WL 2525318 (Fed. Cir. July 7, 2022).[8] Hence, the presumption has been rejected where the differences between the invention and the prior art include, but are not limited, to numerical ranges. *E.g.*, *Forest Lab'ys Holdings Ltd. v. Mylan Inc.*, 206 F. Supp. 3d 957, 1004 (D. Del. 2016) (rejecting presumption of obviousness where "no single reference encompasses the titration schedule claimed in the '220 patent" and "[t]his does not constitute 'overlap'"); *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, No. 10-cv-01376, 2014 WL 1350129, at *13 (S.D. Ind. Mar. 31, 2014) (no "prima facie case of obviousness" because "[w]hile there is some overlap in the ranges" the "overall claimed composition is different").[9]

Here, the Asserted Claims are a unique combination of elements that go far beyond simply adjusting the front and back ends of the intermediate window as

[8] *See also Synvina*, 904 F.3d at 1010 (noting that "the ***only*** relevant difference between these references and claim 1 is in the disclosed ranges of temperature and PO_2"); *In re Kumar*, 418 F.3d 1361, 1366 (Fed. Cir. 2005) ("A prima facie case of obviousness may be made when the ***only*** difference from the prior art is a difference in the range or value of a particular variable.").

[9] *See also Bayer Pharma AG v. Watson Lab'ys, Inc.*, 212 F. Supp. 3d 489, 527 (D. Del. 2016); *Avanir Pharm., Inc. v. Actavis S. Atl. LLC*, 36 F. Supp. 3d 475, 502 n.17 (D. Del. 2014), *aff'd*, 612 F. App'x 613 (Fed. Cir. 2015).

Mylan asserts. JPB at 30-31. For example, Dr. Forrest admitted that using PP1M after a patient had been advanced to PP3M and using PP3M without first stabilizing the patient on PP1M for at least a few months are elements not disclosed in the prior art. JPB 30-31. These elements are not numerical values and are not capable of falling within a prior-art range. Accordingly, the Asserted Claims cannot be reduced to the mere identification of "optimum or workable ranges" and are not subject to a presumption of obviousness. *Aller*, 220 F.2d at 456. Mylan cannot salvage its doomed obviousness case by shifting the burden of proof to Janssen.

2. The *Copaxone* Case Does Not Support Mylan's Position

Mylan repeatedly cites *In Re: Copaxone Consolidated Cases*, 906 F.3d 1013, 1027 (Fed. Cir. 2018), to support its position that a POSA would have been motivated to arrive at the Asserted Claims. MPB at 51, 53, 55-56, 62-63. But *Copaxone* is easily distinguishable, and actually illustrates why the Asserted Claims are nonobvious here. In *Copaxone*, the asserted claims involved treating multiple sclerosis with glatiramer acetate ("GA") 40 mg 3 times a week, whereas the prior art taught treating patients with GA 20 mg or 40 mg either daily or every other day (3.5 days a week). 906 F.3d at 1018-20. Furthermore, several prior art references explicitly "encouraged [POSAs] to pursue a less frequent than daily dosing regimen" because less frequent injections were as effective as daily

injections and caused fewer adverse reactions. *Id.* at 1025. Based on this art, the Court found that it would have been obvious to administer GA 40 mg 3 times a week instead of daily or every other day. *Id.* at 1025-29.

The invention in *Copaxone*—administering the same dose of the same drug for the same condition 3 times, rather than 3.5 times per week, where the prior art provided an explicit motivation to do so—is the kind of dosing-regimen improvement that has been ultimately found obvious. Here, the differences between the prior art and the Asserted Claims are far greater.

As Mylan concedes, the prior art contains no missed dose regimen for PP3M at all; it does not disclose the 4-to-9 month window in the Asserted Claims or any other window for PP3M missed doses; and it does not disclose using PP1M after advancing to PP3M or advancing patients from PP1M to PP3M in fewer than four months. JPB at 30-31; JFF 326. These are the kinds of differences that courts have found to be nonobvious. *See, e.g.*, *Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.*, 571 F. Supp. 3d 281, 300-03 (D.N.J. 2021) (finding novel dosing regimen of Invega Sustenna to be nonobvious over prior-art Invega Sustenna dosing regimen), *appeal filed*, No. 22-1258 (filed Dec. 13, 2021).

F. Mylan Had the Burden to Show Obviousness by Clear and Convincing Evidence

Mylan asserts that because the PP3M references (JAMA, NCT 423[10] and the 2014 Press Release) were "not before the patent office, no deference is owed" to the PTO. MPB at 49-50. Of course, under *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 109 (2011), a clear and convincing evidence standard applies regardless of what references were before the patent office. JPB at 29. Furthermore, the record shows that the PTO is deserving of deference here, because its reasoning in granting the 693 Patent constitutes a rejection of Mylan's obviousness arguments and, in any event, the examiner conducted literature searches that would have identified the relevant art. JPB at 29-30; JFF 21, 24.

Mylan contends that the disclosure in JAMA of "the conversion between PP1M and PP3M" for ***initiating*** patients on PP3M would have led to a different outcome in the PTO. MPB at 50. But the PTO's stated reasons for allowance of the 693 Patent were that no prior art disclosed ***reinitiation*** when PP3M is missed. JFF 25; DTX-8 at 229. Furthermore, the PTO did not have the benefit of the testimony of Dr. Berger that a POSA would ***not*** have been motivated to use the Asserted Claims to reinitiate patients on PP3M. *See supra* 32-33. It nevertheless

[10] Mylan incorrectly argues that results of NCT 423 can be found in the 2014 Press Release. MPB at 48-49, 51; MFF 380. Experts on both sides agree that the 2014 Press Release is about JAMA, not NCT 423. Tr. 451:14-21 (Forrest); JFF 114.

correctly found the claims to be nonobvious. That decision deserves deference.

The PTO also conducted literature searches that would have identified JAMA. JFF 21, 24. Mylan relies on *Sun Pharma Global Fze v. Lupin Ltd.*, No. 18-cv-2213 (FLW)(TJB), 2021 WL 856886, at *4 (D.N.J. Mar. 8, 2021) and *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1573-73 (Fed. Cir. 1983) to argue that the Court should ignore evidence of the PTO's literature searches, but those cases do not help Mylan here. MPB at 49-50. In *Sun*, the plaintiff was expressly permitted to "admit the fact of the search into evidence" through "relevant files from the prosecution history," 2021 WL 856886, at *4, which is exactly what Janssen relies on here. JFF 21 & n.3, 24. *Rohm*, meanwhile, is inapposite because it involves the disclosure of a prior misrepresentation to the PTO by the patentee, which is not the case here, and which of course the examiner could not have found through a literature search. 722 F.2d at 1572-73. Furthermore, *Rohm*, a case from 1983, relied on the "real world conditions under which examiners work." *Id.* By 2015, these conditions included the fact that literature on paliperidone palmitate can be summoned in a matter of seconds using Google Scholar. The record shows that the examiner conducted those very searches. JFF 21, 24. On this record, there is no basis to withhold deference from the PTO's decision. Under any standard, in any event, Mylan has failed to meet its burden of proving obviousness.

G. The Objective Evidence Demonstrates Nonobviousness

The objective evidence corroborates that the Asserted Claims are nonobvious. JPB at 58-67; JFF 347-353. Mylan's post-trial brief fails to refute this. MPB at 70-76. Notably, Mylan fails to address Dr. Kohler's unrebutted testimony that the dosing regimen of the Asserted Claims contributes to his and other clinicians' decisions to prescribe Invega Trinza. JFF 220, 226-227. Rather than confront this direct evidence of nexus, Mylan continues to try to obfuscate the issues, ignore the law, and distort the testimony of Janssen's experts.

1. The Claimed Dosing Regimen Fulfilled a Long-Felt Need

Mylan does not dispute that improving patient adherence was a long-felt need in the treatment of schizophrenia. MPB at 74. Nor does it dispute that missed doses remained a challenge even after the introduction of LAIAs. JFF 219-220; MFF 458. This challenge increases as dosing intervals increase, due to the heightened risk of prolonged side effects and clinicians' "limited knowledge about pharmacokinetics, pharmacodynamics, [and] how long the product lasts to exert clinical efficacy." Tr. 889:15-17 (Kohler). Thus, to ensure the safety and viability of a 3-month LAIA, clinicians needed "clear instructions about how to catch a person up to the previously effective treatment regimen." Tr. 884:8-10 (Kohler). The dosing regimens set forth in the Asserted Claims met this need. JFF 220, 227.

Mylan does not engage with these facts, or even address the substance of Dr.

Kohler's testimony. JPB 61; JFF 219-220. Instead, Mylan argues that Invega Trinza failed to meet a long-felt need because it did not completely solve the challenge of patient adherence in the treatment of schizophrenia. MBP 74-75. But this is not the standard for meeting an unmet need. An invention need not eradicate a condition from the planet to meet a long-felt need for "saf*er* . . . and *more* effective" treatment of disease. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1380 (Fed. Cir. 2006).

The evidence of unmet need is not limited to Dr. Kohler's testimony. Dr. Berger agreed that many of his patients miss a regularly scheduled Invega Trinza dose and return for treatment more than four months after their prior dose, and this was corroborated by the peer-reviewed Joshi paper. JFF 230; PTX-220. Rather than acknowledge this undisputed fact, Mylan has doubled down on its misreading of Joshi to assert that "[n]one of the patients in the Joshi article were prescribed in accordance with the claimed regimen." MFF 75; *see* MPB at 75, 76. This perpetuates a disproven misreading that Mylan advanced at trial. JFF 236. Dr. Stec admitted that Joshi does not contain data to support his reading of the paper (JFF 236), and that it teaches "PP3M was generally administered to schizophrenia patients following the prescribing guidelines." Tr. 1183:14-16 (Stec). Mylan's decision to double down on an incorrect reading of a paper that its own expert renounced at trial highlights the lack of credibility in its response to Janssen's

objective evidence of nonobviousness.

2. The Claimed Dosing Regimens Have Contributed to Invega Trinza's Commercial Success

Mylan appears to have finally conceded that Invega Trinza is a commercial success. MPB at 73. Although Dr. Stec spent much of his testimony suggesting that Invega Trinza's marketplace performance was somehow a failure (without any explanation for how this could be so in light of Invega Trinza's $2.5 billion in sales, *see* JFF 222), Mylan has now limited its arguments regarding commercial success to nexus. MPB at 70-73.

But Mylan continues to misstate the law of nexus. Nexus exists when "customers would be less likely to purchase [a product] without" the feature enabled by the patented invention. *Apple, Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1055 (Fed. Cir. 2016) (en banc). Mylan continues to suggest that nexus requires something more, even after Dr. Stec admitted that a claimed invention need not be the only or even primary cause of success. Tr. 1167:18-19 (Stec); JFF 234. Mylan relies on *Campbell Soup Co. v. Gamon Plus, Inc.*, 10 F.4th 1268, 1277 (Fed. Cir. 2021) to argue that commercial success must be "a direct result" of the claimed invention as the newest source of an ambiguous higher threshold. MPB at 71. But in *Campbell Soup*, nexus was missing because the elements of the soup can display rack label that "ma[de] a difference" for customer behavior were not part of the claimed invention. 10 F.4th at 1278. The Federal Circuit did not

question that there could be nexus between the design of a soup can display rack label and the commercial success of the soup, if there had been evidence that the patented features "ma[de] a difference."[11] *Id.* at 1278-79. Here, Dr. Kohler presented such evidence, and Mylan failed to rebut it. JFF 226-231.

Finally, Mylan reprises the argument that the nexus analysis requires "separating out" the influence of other drivers of success. MPB at 73. But, as Dr. Stec admitted, there is no requirement to quantitatively separate the various causes of a product's commercial success to establish a nexus. Tr. 1173:10-24 (Stec). And, in any event, Ms. Mulhern *did* account for many other causes or potential causes of Invega Trinza's commercial success—including the paliperidone palmitate molecule—and concluded that these other factors did not fully account for the success of the product. Tr. 1096:21-1099:19 (Mulhern).

3. Clinicians Were Skeptical of the Claimed Dosing Regimen

It is undisputed that HCPs, prominently including Dr. Berger, were "skeptical about . . . the workability" of the innovative missed dose regimen disclosed in the Asserted Claims. *WBIP LLC v. Kohler Co.*, 829 F.3d 1317, 1335 (Fed. Cir. 2016); *see* JPB at 67; JFF 239-240. Mylan does not mention skepticism in its post-trial brief, making no effort to mitigate Dr. Berger's testimony that

[11] This is true even though a soup can display rack is not the only, or even the primary, reason that consumers buy Campbell's soup.

following the Asserted Claims is "unsafe," "unreasonable," and a "bad idea." Tr. 262:9-263:9, 1043:5-10 (Berger); JFF 239; *see* FPTO at 111. To the contrary, Mylan endorses Dr. Berger's skepticism. MPB at 2, 24. Dr. Berger's skepticism provides powerful evidence of the nonobviousness of Janssen's invention.

III. MYLAN FAILED TO ESTABLISH THAT THE ASSERTED CLAIMS LACK ENABLEMENT

At trial, Mylan fell far short of meeting its burden of establishing that the Asserted Claims are invalid for lack of enablement. Mylan failed to make the threshold showing for enablement, i.e., that experimentation is required to make and use PP1M and PP3M in the Asserted Claims, failed to identify any non-enabled formulations, and failed to show that any one of the relevant factors supports non-enablement. JPB at 68-80. Nothing in its post-trial briefing corrects these deficiencies.

1. PP1M and PP3M Are Defined By the Structural Limitations in the Specification

At trial, Dr. Forrest presented Mylan's non-enablement argument that the terms PP1M and PP3M are unduly broad because they are defined by particle size ranges and classes of excipients rather than precise particle sizes and specific excipients. JFF 245, 260. Janssen addressed these arguments in its initial briefing and will revisit them below. JPB at 73-78; *see infra* at 51-52. In its post-trial brief, however, Mylan introduces a different argument, asserting that the claims are

unduly broad because PP1M and PP3M have ***no*** structural limitations. MPB at 79-80. Mylan's position is contradicted by both parties' experts, who ***agree*** that the claim terms PP1M and PP3M are limited to formulations having the structural features described in the 693 Patent specification. JPB at 75.

Dr. Little testified at length that the structural features in the 693 Patent—including the ingredients, concentrations, and particle size ranges—provide the "recipe" for PP1M and PP3M. JPB at 73-78. Mylan blatantly mischaracterizes the record by contending that Dr. Little "agrees that the claims cover all particle sizes."[12] MFF 496. But the actual portion of Dr. Little's testimony cited by Mylan clearly states that particle size is defined in the specification. MFF 496 (citing Tr. 970:2-6 ("**Q.** I want to talk a little bit about . . . particle size. Is particle size mentioned in the claim language? **A.** In the actual claim language, no. That's in the specification as well . . . ."). And his testimony overall made it abundantly clear that he understood PP1M and PP3M were limited to those particle size ranges. JFF 250, 280 n.23 (testifying to differences between PP1M and PP3M particle size range).

Dr. Forrest was similarly clear that PP1M and PP3M are defined by the structural information in the patent specification. Indeed, the crux of his testimony

[12] Mylan made numerous such mischaracterizations. *See also* MFF at 500 (mischaracterizing Dr. Little as "implicitly agreeing to the breadth of the asserted claims").

was that the structural features in the specification were too broad, not that the terms PP1M and PP3M had no structural limitations:

> So, because I just claimed a formulation and don't recite structural elements there, ***you have to go to the specification to understand what a PP1M and what a PP3M encompasses***. The specification just provides broad ranges of excipients and types of excipients and concentrations, and then broad ranges of particle sizes that could be used.

Tr. 517:1-6 (Forrest).

With both parties' experts agreeing that the structural features in the specification identify "what a PP1M and what a PP3M encompasses," Mylan's contention that there are "no metes and bounds" to PP1M and PP3M "that could inform the public as to where such formulations begin or end" is directly contrary to the trial record. MPB at 79-80.

Nor does Mylan's argument have any support in the law. Mylan does not dispute that the scope of technical terms is understood in light of the specification. *Multiform Desiccants, Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998) ("The best source for understanding a technical term is the specification from which it arose."); *see, e.g., GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 727-28 (Fed. Cir. 2014) (construing structural features of the term "solvate" based on specification); *see also Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1184 (Fed. Cir. 2014) ("The court construed the claim term

'prostaglandin' to correspond to the disclosure in the written description of the patents regarding the prostaglandins that may be used with the invention."). Here, both experts understand PP1M and PP3M to "encompass" the structural features in the specification of the 693 Patent. JPB at 75; *see also* JFF 246, 259. Mylan's argument to the contrary fails.

2. The Terms PP1M and PP3M Are Not Unduly Broad

Turning to the arguments Mylan's expert actually proffered at trial, Janssen has already addressed the erroneous contention that PP1M and PP3M encompass "millions" of formulations and are unduly broad because they are defined by particle size range and by excipient classes. JPB at 75-78. As Dr. Little explained, a POSA would view the 693 Patent's disclosure of PP1M and PP3M as describing a singular formulation for each, within which specified variation is allowed in well-known classes of excipients and standard particle size ranges. JPB at 75-78.

[redacted]. JPB at 77-78. Dr. Little's testimony was also corroborated by Dr. Forrest's concessions that particle size ranges and long lists of excipients are standard to describe formulations, as well as by Dr. Forrest's patents, describing and claiming formulations with much larger particle size ranges (10,000-fold) and long lists of excipients. JPB at 76-78. Any suggestion that

formulations cannot be described by particle size range or with lists of excipients fails to incorporate the perspective of a POSA. JPB at 75-78. Dr. Forrest's conclusory testimony that the claims are too broad to be enabled lacks support and cannot be squared with the record.

3. There is No Evidence of Undue Experimentation

In its post-trial brief, Mylan asserts that the "inquiry for enablement . . . compare[s] the scope of the claims to the disclosure of the specification." MPB at 76. Janssen has already shown that there is no significant disparity between the claims and disclosure. JPB at 73-78. Furthermore, Mylan's framing is incomplete. Claim scope and patent disclosure are not considered in a vacuum, but as part of the *Wands* factors for "determining whether a disclosure would require undue experimentation." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Mylan cannot show that the claim breadth or patent disclosure results in undue experimentation.

Mylan contends that Janssen had to "identify which excipients and particle sizes would work in the manner set forth by the claims, i.e., to reinitiate patients safely and effectively on PP3M after they have missed a scheduled dose." MPB at 82. But that is precisely what Janssen did: it set forth the recipe-like disclosure that a POSA would "trust" to make PP1M and PP3M and use them in the Asserted Claims. JPB at 71-72. [redacted]

[redacted]. JFF 269.

Mylan argues that every variation within the defined particle size ranges and excipient classes for PP1M and PP3M must be tested, because "particle size and structural elements impact the pharmacokinetics" and "different formulations would be likely to result in different pharmacokinetics." MPB at 77, 80. For this point, Mylan relies on Dr. Gobburu's testimony that "[i]f you change the formulation, one cannot predict the pharmacokinetics of the new formulation." MPB at 80 (citing MFF 494). But this testimony does not help Mylan. Dr. Gobburu was testifying about what a POSA would have known based on the prior art relied on by Dr. Forrest. JFF 168-169, 275-277. He did not address the structural features disclosed in the 693 Patent, and indeed admitted that, as an expert in pharmacokinetic modeling rather than formulations, he was not qualified to do so. JFF 276. Thus, contrary to Mylan's mischaracterization, Dr. Gobburu did not testify that changes ***within the ranges defined by the 693 Patent*** result in meaningfully different properties for purposes of the claims. JFF 276. By relying on Dr. Gobburu's testimony, Mylan conflates the critical difference between obviousness and enablement. MPB at 80. A POSA without the 693 Patent would have no idea how to arrive at the claimed dosing regimens, but a POSA with the 693 Patent would have little difficulty practicing them.

Mylan also cites Janssen's statement during prosecution of the 693 Patent that the different nanoparticle sizes of PP1M and PP3M make them "vastly different" formulations. MPB at 80. But the fact that PP1M and PP3M have different particle size ranges and different properties ***from one another*** has no bearing on changes ***within*** the scope of each formulation. JFF 274-277. Mylan has not proffered a shred of evidence that changes to particle size or structural elements within the definitions of PP1M and PP3M result in meaningful changes that require experimentation. JPB at 71; JFF 273-277.

4. Mylan's Case Law Highlights Mylan's Failure of Proof

The cases Mylan relies on in support of its enablement case only serve to illustrate that Mylan has failed to prove non-enablement here. MPB at 77-82. In each case, there was evidence of non-enabled portions of the claims or of extensive experimentation. Here, there is no such evidence. JPB 70-73.

For example, Mylan cites *Wyeth and Cordis Corp. v. Abbott Laboratories*, 720 F.3d 1380, 1385 (Fed. Cir. 2013) as an example of undue experimentation. MPB at 80-81. In *Wyeth*, it was undisputed that the claims covered millions of compounds but that only a "significantly smaller" number would exhibit the claimed functional effects. *Id.* at 1384. It was also undisputed that experimentation was required to "first synthesize and then screen each candidate compound" to check for the required functional properties. *Id.* at 1385. The court

found the experimentation undue because the synthesis could "require a complicated and lengthy series of experiments" and it would take "weeks to complete" the screening assays. *Id.* at 1386. By contrast, here there is no evidence that (1) only a subset of PP1M or PP3M formulations can be used in the Asserted Claims,[13] (2) screening is required for changes made within the PP1M and PP3M recipes, or (3) any screening would take time. JPB at 70-73. *Wyeth* illustrates what is required to show non-enablement, and here Mylan failed to meet those requirements.

Sitrick v. Dreamworks, 516 F.3d 993 (Fed. Cir. 2008) and *MagSil Corp. v. Hitachi Global Storage Technologies, Inc.*, 687 F.3d 1377 (Fed. Cir. 2012) are similarly unhelpful to Mylan. MPB at 77-78. In *Sitrick*, the court found the specification did not enable claims for integrating a user's audio signal or visual image into a video game ***or*** movie because it did not teach integration in movies. 516 F.3d at 1000. And in *MagSil*, while the patent claimed a tri-layer tunnel junction device wherein applying electromagnetic energy causes a change in the resistance "by at least 10%" (construed to cover changes up to infinity), there was evidence that the inventors could not achieve greater than 20% resistance. 687 F.3d

[13] For the same reason, Mylan's reliance on *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, 941 F.3d 1149, 1159 (Fed. Cir. 2019) is misplaced. MPB at 81. In *Idenix*, the patentee had ***conceded*** that not all the compounds within the claim would have the required activity against Hepatitis C virus. *Id.* There is no such evidence here. JPB at 72-73.

at 1382.

Here, in contrast, Mylan has not identified a subset of the purportedly broad terms PP1M and PP3M that a POSA could not make or use. Without such a showing, Mylan cannot establish non-enablement. JPB at 72-73; *Alcon*, 745 F.3d at 1189. Mylan's enablement challenge is based on the "abstract possibility" that PP1M and PP3M are not enabled and that is insufficient to satisfy its high burden. *McRO, Inc. v. Bandai Namco Games Am., Inc.*, 959 F.3d 1091, 1100 (Fed Cir. 2020); JPB at 72-73.

IV. MYLAN FAILED TO ESTABLISH THAT THE ASSERTED CLAIMS LACK WRITTEN DESCRIPTION

Finally, Janssen established that the 693 Patent provides an adequate written description of the structure of PP1M and PP3M by disclosing the ingredients, concentrations, and particle size range of each. JPB at 81-82. Mylan's submission does not disturb this straightforward analysis. JPB at 80-83.

Mylan does not dispute that an "adequate written description" can be provided by "a precise definition, such as by ***structure***." JPB at 81 (quoting *GlaxoSmithKline*, 744 F.3d at 730 (emphasis in original)). To avoid this case law, Mylan contends that "the claims cover *any* PP1M and PP3M formulation," without any structural limitation. MPB at 83. But as discussed above, that is simply not correct. Both parties' experts agreed that PP1M and PP3M are limited to the structural features disclosed in the specification. *Supra* at 48-51. Mylan's written

description argument therefore fails. JPB at 80-83.

Later in its brief, Mylan effectively concedes this point, asserting that "Janssen claimed . . . PP1M and PP3M, using general and wide ranges of elements of such formulations in the specification." MPB at 83. But those "general and wide ranges," as Mylan calls them, are the very structural features that satisfy the written description requirement and include a detailed recipe-like disclosure of ingredients, concentrations, and particle sizes for PP1M and PP3M. JFF 246-250; PTX-1 at 13:62-14:3, 13:49-56, 10:1-30, 13:3-13, 4:33-39, 13:56-61, 14:9-13, 9:38-61. Mylan has not shown that these structural features fail to provide an adequate written description or otherwise show that the inventors did not possess the subject matter of the claims. JPB at 81.

Mylan argues that "[o]ther than the two formulations described in the specification, Janssen did not have possession of the recited PP1M or PP3M formulations that fall within the scope of the claims."[14] MPB at 83. But as the trial record showed, a POSA would view the disclosures of PP1M and PP3M as describing two formulations with defined variability in particle size and excipients, not as broad terms covering millions of individual formulations. JPB at 81-82.

More critically, the test for written description is not how many examples

[14] Evidently, even Mylan recognizes that Dr. Forrest's testimony that there are "no working examples" of PP1M and PP3M in the 693 Patent is wrong. JFF 258.

the patentee made. JPB at 83. On this point, *Alcon Research Ltd. v. Barr Laboratories, Inc.*, 745 F.3d 1180 (Fed. Cir. 2014) is instructive. JPB at 83. There, the Federal Circuit rejected defendant's argument that the claims lacked written description because the "specifications only disclose physical data from ***one compound***." *Alcon,* 745 F.3d at 1190. The court explained that "[t]here is no requirement that the disclosure contain either examples or an actual reduction to practice" at all, and clarified that the "critical inquiry is whether the patentee has provided a description that in a definite way identifies the claimed invention in sufficient detail that a [POSA] would understand that the inventor was in possession of it at the time of filing." *Id.* at 1190-91 (internal quotation marks omitted).

In *Alcon*, the patent claimed a method of enhancing the chemical stability of an aqueous composition of prostaglandin by adding polyethoxylated castor oil ("PECO"). *Id.* The specification included, *inter alia*, classes of prostaglandins, "preferred examples of those prostaglandins," "exemplary formulations," "various formulation parameters, including osmolality and pH, that may be selected when practicing the invention," and "various types of PECOs that may be used," along with preferred PECOs and concentrations. *Id.* The 693 patent has a very similar disclosure of the ingredients, concentrations, and particle sizes, including preferred ingredients, concentrations, and formulations alongside exemplary embodiments.

JFF 246-250. The "disclosure[] demonstrates that the inventors possessed the claimed invention: they conceived of and described the invention at the time the" patent was filed and "[t]hat is all that the written description requirement demands. *Alcon*, 745 F.3d at 1191. The same is true here. Mylan's written description arguments fail.

CONCLUSION

For the reasons discussed above and in Janssen's opening post-trial submissions, Mylan's Proposed Labels induce infringement of the Asserted Claims and Mylan failed to prove that the Asserted Claims are invalid as obvious, non-enabled, or inadequately described. Mylan's post-trial submissions only serve to underscore the defects in Mylan's case. The Court should enter judgment in Janssen's favor.

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CERTIFICATE OF SERVICE

I certify that on February 21, 2023, I caused true and correct copies of Plaintiffs' Responsive Post-Trial Brief to be served via e-mail on all counsel of record.

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